510(k) Summary

AUG 3 1 2006

ConforMIS, Inc.

Total Knee Repair System

510(k) Notification K052687

GENERAL INFORMATION

Manufacturer:

ConforMIS, Inc.
323 C Vintage Park Drive
Foster City, CA 94404
Phone 650-286-4151
FAX 650-286-4160

Contact Person:

Patrick Hess, PhD
Chief Executive Officer
ConforMIS, Inc.

Date Prepared:

August 28, 2006 (revised)

DEVICE INFORMATION

Trade/Proprietary Name

Tri-Compartmental Resurfacing (tCR) Device

Common/Classification Name

Knee joint patellofemorotibial cemented prosthesis

21 CFR 888.3560 – Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis.

Class II

Device Product Code: JWH

PREDICATE DEVICES

The ConforMIS, Inc. Tri-Compartmental Resurfacing (tCR) Device is substantially equivalent to FDA-approved predicate devices with regard to indications for use and technological characteristics. These predicate devices are:

Technological Characteristics	Indications for Use
• ConforMIS Knee Interpositional Device (K033242) • ConforMIS Unicompartmental (K043570)	• Biomet Anatomic Total Knee Prosthesis(K000978) • Advance® Total Knee system (K974328) • Alaron Surgical Active Knee® System (K021740)

INTENDED USE

The ConforMIS Tri-Compartmental Resurfacing (tCR) Device is intended for use in patients with severe knee joint pain and disability. The indication for use include restoring joint function and relief of pain due to:

- painful joint disease due to osteoarthritis, traumatic arthritis or rheumatoid arthritis of the knee
- post traumatic loss of joint function
- valgus or varus deformity of the knee

The ConforMIS *Tri*-Compartmental Resurfacing (tCR) Device is intended for use only with bone cement.

PRODUCT DESCRIPTION

The ConforMIS, Inc., Tri-Compartmental Resurfacing (tCR) Device is a tri-compartmental semi-constrained total knee implant. The design of the product incorporates a bone preserving approach, with minimal bone resection of the tibia and femur, for the treatment of severe pain and/or disability of a knee damaged by osteoarthritis or trauma. Using patient imaging (either MRI or CT scans) a patient specific implant is designed that best meets the geometric and anatomic requirements of the specific patient. The treatment allows for the placement of a cemented metallic device designed from the patient's natural bone geometry. The femoral component is manufactured from cobalt chromium molybdenum alloy (ASTM-F-1537) from specific design drawings created from data obtained from images of the patient's individual geometry obtained using either MRI or CT scans. ConforMIS, Inc., implant Software is used to remove surface defects to produce a working design image of a smooth surface. Off the Shelf (OTS) software is utilized to produce the surface design. Subsequently, Solid Works OTS software is used to create the ConforMIS, Inc. Implant Engineering

Drawing. The implant is manufactured using multiple SLA and standard casting techniques.

The tibial component is manufactured from UHMWPE (ASTM-F-648) from a drawing produced in a similar manner to the femoral component. It is individualized on its footprint to match the patient's tibial anatomy. The articular surface is designed to be flat in the periphery and slightly concave in the femoral contact area. The all polyethelene (UHMWPE) component is designed for use with bone cement and central cement retention features will be incorporated on the undersurface of the implant. The circumferential size and shape of the tibial component are designed to be 1-3mm within the articulating surface borders of the tibia at the cut bone depth. The minimal poly thickness is 7mm and the component is designed to replace a bone cut of 2-6mm (measured distally from the lowest point of the bony surface of the affected condyle).

The patellar component is also manufactured from UHMWPE.

SUBSTANTIAL EQUIVALENCE

Technological Characteristics

The technological characteristics of the ConforMIS, Inc., Tri-Compartmental Resurfacing (tCR) Device are substantially equivalent to those of the cited predicate orthopedic devices. The image analysis is identical with that used for the ConforMIS interpositional device (iPD) and the ConforMIS unicondylar implant. This device is equivalent in terms of design process, materials, production process, and equipment.

Indications for Use

Substantial equivalence is also supported for the ConforMIS, Inc., Tri-Compartmental Resurfacing (tCR) Device by the predicate devices previously cited and cleared in the treatment of osteoarthritic knees where total knee replacement is warranted.

TESTING IN SUPPORT OF SUBSTANTIAL EQUIVALENCE DETERMINATION

The device design was evaluated using standardized fatigue, constraint and contact area biomechanical testing. The results of this testing provide objective support for the claim of substantial equivalence.

SUMMARY

Based on the similarities in design, materials, function, and intended use, the ConforMIS, Inc., Tri-Compartmental Resurfacing (tCR) Device is substantially equivalent to the devices currently marketed under the Federal Food, Drug and Cosmetic Act. In addition, the ConforMIS, Inc. Tri-Compartmental Resurfacing (tCR) Device raises no new safety or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Dr. Patrick Hess
Chief Executive Officer
ConforMIS, Inc.
323 C Vintage Park Drive
Foster City, California 94404

AUG 3 1 2006

Re: K052687
Trade/Device Name: ConforMIS Tri-compartmental Resurfacing Device
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWH
Dated: August 15, 2006
Received: August 16, 2006

Dear Dr. Hess:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0210 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Buchman for

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): #K052687

Device Name: ConforMIS Tri-compartmental Resurfacing Device

Indications for Use:

The ConforMIS Tri-compartmental Resurfacing Device (tCR)is a minimally invasive, bone preserving primary total knee system intended for use in patients with severe knee joint pain and disability. The indications for use include restoring joint function and relief of pain due to:

- Painful joint disease due to osteoarthritis, traumatic arthritis, rheumatoid arthritis of the knee
- Post traumatic loss of joint function
- Mild to moderate valgus or varus deformity of the knee

The ConforMIS Tri-compartmental Resurfacing (tCR) Device is intended only for use with bone cement.

Prescription Use XX (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Ruelland

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

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510(k) Number K052687